

EUROPEAN HEALTH DATA SPACE: CRUCIAL PROPOSAL FOR BETTER DISEASE PREVENTION, DEVELOPMENT OF MEDICINES AND CROSS-BORDER HEALTHCARE

Health insurance funds and health mutuals of AIM welcome the proposal for an EU regulation on the European Health Data Space, which was published on 3 May 2022 by the European Commission. It is a framework that establishes clear rules on developing common standards and establishing infrastructures as well as a governance framework for the use of sensitive health data by patients, policymakers, innovators and researchers. It is therefore an opportunity to improve better disease prevention, while putting the interests of better health in the centre of attention. Health insurance funds and health mutuals are key stakeholders when it comes to health data.

Telemedicine as an important step for cross border healthcare

AIM members welcome that telemedicine is included in the context of cross-border healthcare and that it is treated the same way as the provision of services of the same type provided physically by a healthcare provider located in a Member State. The COVID-19 pandemic has shown that digital health services have become an important part of healthcare delivery. Cross-border healthcare is only functioning if all Member States are equipped equally for cross-border patient data sharing. The access to personal electronic health data by health professionals independently of the Member State of affiliation and the Member State of treatment, as suggested in the proposal, is therefore an important and necessary step. AIM members welcome that patients have the possibility to restrict the access to their personal health data to ensure data privacy.

The European Health Data Space as secure environment for data reuse

AIM members support Commissioner Kyriakides that “the European Health Data Space requires an additional layer of security protection compared to the already strong EU’s privacy framework so that citizens can “be confident that their personal health data will be handled with the greatest care, and it will be underpinned by very strong data protection and data security.” The Data protection framework and its varying implementations across member states have created an unnecessarily fragmented landscape, which has led to uncertainty. AIM welcomes that researchers, innovators and policymakers have to apply for a permit to be able to reuse health data, that accessing, and processing of health data has to be in a “secure processing environment” and that only anonymous data can be reused. However, AIM would like to emphasize that the permit process for health data should be organized effectively, to avoid situations like the process related to the Medical Devices. The Medical Devices Regulation is currently a bottleneck for innovators to enter the market. Organisations that had to handle the certifications were overloaded with certification requests, which is still the case today. When introducing a certification procedure for the European Health Data Space, lessons should be learned to ensure that an efficient and unified certification process is put in place. In addition, data access bodies operating differently, leading to different speeds of approval or different execution of approval processes, risking different criteria setting, should be avoided.

Digital health/data literacy is necessary to avoid widening the inequality gap

AIM regrets that digital health/data literacy is not mentioned in the proposal. The EU should invest in and promote the equal development of a basic understanding of digital health/data literacy and skills (e-health, m-health literacy) in the Member States for the public at large to empower the citizen in healthcare and the citizen's knowledge on their health data. Citizens need to understand that they have the right to give and revoke an approval to use their data. In addition, they must be given the tools to manage their approvals (also for digital-illiterate citizens). Digital health/data literacy and skills should be promoted in the formation for healthcare professionals and a point of attention in (continued) education. Researchers and academics should be aware of the legal framework that applies to the digital exchange of health data.

Secondary use of health data will lead to higher quality of care rather than bottom line-savings

The Commission proposal mentions EUR 3.4 billion financial benefits thanks to more efficient secondary use of health data and EUR 0.3 and EUR 0.9 billion financial benefits thanks to access to more innovative and medical products and better decision-making. AIM members emphasize that this will only be achieved over a long period of time and therefore will be hard to prove. We agree that the secondary use of health data as well as more innovative and medical products and better decision-making will lead to a higher quality of care.

Enhancing interoperability of electronic health data should be a high priority at nation level

AIM welcomes the fact that the Commission proposes the creation of an expert group that assists and prepares delegated acts to "enhance the interoperability of electronic health data for healthcare, building on existing European, international or national standards and experience of other data spaces". It should be noted that achieving this standardization at European level is a very complex task, and that should be a high priority for the national organizations to put the European Health Data Space into effect.

AIM will contribute to the discussions and has been selected as an advisor in TEHDAS.

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The International Association of Mutual Benefit Societies (AIM) is an international umbrella organisation of federations of health mutuals and other not-for-profit healthcare payers. It has 55 members from 28 countries in Europe, Latin America and Africa and the Middle East. AIM members provide compulsory/and/or supplementary health coverage to around 230 million people around the world, including close to 200 million people in Europe, on a not-for-profit basis. Some AIM members also manage health and social services. Collectively, they have a turnover of almost €300 billion. Members are either mutual or health insurance fund. They are private or public legal entities; solidarity based; not-for-profit orientations: surpluses are used to benefit the members; democratically-elected members play a role in the governance of the organisation.

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